

**§ 607.35 Notification of registrant; blood product establishment registration number and NDC Labeler Code.**

(a) The Director of the Center for Biologics Evaluation and Research will provide to the registrant a validated copy of Form FD-2830 (Blood Establishment Registration and Product Listing) as evidence of registration. This validated copy will be sent to the location shown for the registering establishment, and a copy will be sent to the reporting official if at another address. A permanent registration number will be assigned to each blood product establishment registered in accordance with these regulations.

(b) If a registered blood product establishment has not previously participated in the National Drug Code system, or in the National Health Related Items Code system, the National Drug Code (NDC) numbering system shall be used in assigning the first five numeric characters, otherwise known as the Labeler Code, of the 10-character NDC Code. The Labeler Code identifies the manufacturer.

(c) Although establishment registration and blood product listing are required as described in § 607.20, validation of registration and the assignment of a NDC Labeler Code do not, in themselves, establish that the holder of the registration is legally qualified to deal in such products.

[40 FR 52788, Nov. 12, 1975, as amended at 49 FR 23833, June 8, 1984; 66 FR 59159, Nov. 27, 2001]

**§ 607.37 Inspection of establishment registrations and blood product listings.**

(a) Any registration on Form FDA 2830 (Blood Establishment Registration and Product Listing) filed in paper or electronic format by the registrant will be available for inspection under section 510(f) of the act, through the Center for Biologics Evaluation and Research Blood Establishment Registration Database Web site by using the CBER electronic Web-based application or by going in person to the Food and Drug Administration, Division of Dockets Management Public Reading Room (see address in § 20.120(a) of this chapter). The following information

submitted under the blood product listing requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

- (1) A list of all blood products.
- (2) A list of all blood products manufactured by each establishment.
- (3) A list of blood products discontinued.
- (4) All data or information that has already become a matter of public knowledge.

(b) Other requests for information regarding blood establishment registrations and blood product listings should be directed to the Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993-0002.

[80 FR 18092, Apr. 3, 2015]

**§ 607.39 Misbranding by reference to establishment registration or to registration number.**

Registration of an establishment or assignment of a registration number or assignment of a NDC number does not in any way denote approval of the firm or its products. Any representation that creates an impression of official approval because of establishment registration or possession of registration number or NDC number is misleading and constitutes misbranding.

**Subpart C—Procedures for Foreign Blood Product Establishments**

**§ 607.40 Establishment registration and blood product listing requirements for foreign blood product establishments.**

(a) Every foreign establishment shall comply with the establishment registration and blood product listing requirements contained in subpart B of this part, unless exempt under subpart D of this part or unless the blood product enters a foreign trade zone and is re-exported from that foreign trade zone without having entered U. S. commerce.

(b) No blood product may be imported or offered for import into the United States unless it is the subject of